

NASULGC National Association of State Universities and Land-Grant Colleges

April 22, 2004

Dr. Mark Rohrbaugh
Director of the Office of Technology Transfer
Office of Intramural Research
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, MD 20852

Dear Dr. Rohrbaugh:

On behalf of the National Association of State Universities and Land-Grant Colleges ("NASULGC"), the Association of American Universities (AAU), and the American Council on Education ("ACE"), we are writing to share our views about the two petitions filed with the National Institutes of Health (NIH) to exercise Bayh-Dole march-in rights to require Abbott Laboratories to lower the price of several drugs developed from NIH extramural research.

The petitions are rooted in the proposition that march-in rights can be exercised to maintain the accessibility and affordability of an essential medical invention. Neither the plain meaning nor the public policies that undergird the Bayh-Dole Act permit a march-in based on affordability. March-in is not a surrogate for government price controls on products that result wholly or in part from federal funding. March-in is reserved only for the purpose of prompt commercialization of federally funded inventions and to avoid the possibility of the stifling of new product development.

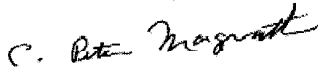
The subject of delivering affordable health care to the American public is a serious one, worthy of policy debate; it is ongoing in Congress in the context of Medicare reform and drug reimportation. Debate about the quality and accessibility of health care is especially worthwhile when life-saving drugs involving potentially fatal diseases, such as HIV-AIDS, are involved. But, the Bayh-Dole Act is not the proper forum for this debate. The Act does not confer regulatory authority on the NIH to impose price controls either globally or on a case-by-case basis. Nor should the Patent Act, in which the Bayh-Dole Act resides, be used as a compulsory mechanism for reasonable drug pricing.

If the NIH were to interpret its authority so as to exercise march-in rights, we are deeply concerned that the Bayh-Dole Act, one of this country's most successful statutes, could be subjected to a litany of unintended consequences. The ability of universities to make their federally funded technologies available for public benefit would be undermined, and the incentive for the private sector to invest in federally funded discoveries would be removed. In the final analysis, the synergy between federal funding, university research and the private sector for product development could be lost.

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In short, the Bayh-Dole Act has become a driving force for successful research activities from which the U.S. economy and the American public have benefited. Any administrative action taken by the NIH must recognize the success of the Act and its limitations as a price-control mechanism.

Cordially,



C. Peter Magrath
President, NASULGC



Nils Hasselmo
President, AAU



David Ward
President, ACE

CPM/rh